K011569

FEB 2 2 2002

510(k) Summary
Bionx Implants Inc.'s
BioSorbFX™ O/M 2.0/2.4 Bioabsorbable Fixation System

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Blue Bell, PA 19422

Contacts: Gerard S. Carlozzi
President and Chief Executive Officer
Phone: (215) 643-5000
Facsimile: (215) 653-0984

Bionx Implants Ltd.
Tuija Annala
Quality Manager
P.O.Box 3
FIN-33721 Tampere
Finland
Phone: 358-3-316 5679
Facsimile: 358-3-316 5629

Date prepared: February 22, 2002

Name of the Device: BioSorbFX O/M 2.0/2.4 Bioabsorbable Fixation System

Common or Usual Name:
Bioabsorbable Craniofacial Bone Plates and Plate Fasteners

Classification Name: Bone Plate and fasteners (Product Code 76 JEY)

Predicate Devices:
1. Bionx Implants, Inc. BioSorbFX™ 1.5/2.0 Bioabsorbable Fixation System ("BioSorbFX™ 1.5/2.0 System") (K982139)
2. Bionx Implants, Inc. BioSorbFX™ O/M 2.0/2.4 Bioabsorbable Fixation System ("BioSorbFX™ O/M 2.0/2.4 System") (K982721)
3. Biomet Inc. 2.5mm LactoSorb® Screws (K981666)
4. Biomet Inc. LactoSorb® Sheets (K992158)
5. Synthes SMF Resorbable Meshes and Sheets (K003786)
6. Lorenz Resorbable Distractor System (K002083)
7. Macropore MacroporeMX Mandibular Fixation System (K000096)

8. Macropore Protective Sheet (K983360)

Intended Use

The BioSorbFX O/M 2.0/2.4 System is intended for use in trauma and reconstructive procedures in the midface, maxilla and mandible. Specifically, the device is indicated for use in surgical repair procedures in the treatment of trauma to the midface, maxilla and mandible, and in orthognathic and reconstructive procedures of the midface, maxilla or mandible. The BioSorbFX O/M 2.0/2.4 System stabilizes bone during healing, in conjunction with appropriate postoperative immobilization. When used in the mandible, the BioSorbFX O/M System must be used in conjunction with appropriate maxillomandibular fixation (MMF).

The BioSorbFX O/M 2.0/2.4 System implants are not intended for use in and are contraindicated for:

1. Mandibular tumor resection.
2. Situations where internal fixation is otherwise contraindicated e.g., active or potential infection; patient conditions, including blood supply limitations, insufficient quantity or quality of bone; and where patient co-operation cannot be guaranteed (e.g., alcoholism).
3. Significant comminuted fractures, including significant bone loss, of the mandible.
4. Intermaxillary fixation without an appropriate external fixation by other means.

Technological Characteristics and Substantial Equivalence

The BioSorbFX™ O/M 2.0/2.4 Bioabsorbable Fixation Systems consists of various plate configurations, which are attached to the bone by 2.0, 2.4 and 2.8mm threaded fasteners (i.e., screws) of various lengths. The specifications for the BioSorbFX™ O/M 2.0/2.4 System plates and fasteners will require a self-reinforced copolymer derived from L-lactide and D/L-lactide ("PLA copo."), which consists of 70 molar percent poly-L-lactide and 30 molar percent poly-D,L-lactide, with strength retention time 18-36 weeks.

Properly used, in the presence of adequate immobilization, absorbable BioSorbFX™ O/M 2.0/2.4 System implants stabilize bone during healing. The BioSorbFX™ O/M 2.0/2.4 System implants gradually lose their strength during 18-36 weeks. Biodegradation takes place within two to three years. The BioSorbFX™ O/M 2.0/2.4 System includes an instrument set containing bone drills, bone taps, screwdrivers, plate benders and cheek retractors. This instrument set is identical with the previously cleared BioSorbFX™ 2.0/2.4 System (K982721) and substantially equivalent with the previously cleared BioSorbFX™ 1.5/2.0 System (K982139) and BioSorb™ Endobrow Screw™ (K972919).

The BioSorbFX™ O/M 2.0/2.4 System has the same intended use and principles of operation and is substantially equivalent to the devices previously cleared by FDA including the Bionx Implants Inc. BioSorbFX™ 2.0/2.4 System (K982721),

BioSorbFX™ 1.5/2.0 System (K982139), Biomet, Inc. 2.5mm LactoSorb® Screws (K981666) and LactoSorb® Sheets (K992158), Synthes SMF Resorbable Meshes and Sheets (K003786), Lorenz Resorbable Distractor System (K002083), Macropore MacroporeMX Mandibular Fixation System (K000696) and Macropore Protective Sheet (K983360).

The BioSorbFX O/M 2.0/2.4 System has following similarities with previously cleared BioSorbFX 2.0/2.4 System (K982139):

- Uses the same operating principles
- Incorporates the same basic design
- Is manufactured, packaged and sterilized using the same machinery and processes.

The BioSorbFX O/M 2.0/2.4 System has following similarities with previously cleared Biomet Inc. 2.5mm LactoSorb® Screws (K981666) and LactoSorb® Sheets (K992158), Synthes SMF Resorbable Meshes and Sheets (K003786), Lorenz Resorbable Distractor System (K002083), Macropore MacroporeMX Mandibular Fixation System (K000696) and Macropore Protective Sheet (K983360).

- Uses the same operating principles
- Incorporates the same design principles
- Is used for similar indications

In summary the BioSorbFX O/M 2.0/2.4 System described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Bionx Implants, Incorporated
Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Bionx Implants, Limited
Hermiankatu 6-8 L
Tampere,
FINLAND

Re: K011569
Trade/Device Name: BioSorbFX™ O/M 2.0/2/4 System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: November 22, 2001
Received: November 26, 2001

Dear Ms. Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

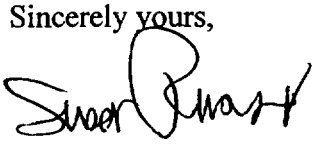
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): _____

Device Name: BioSorbFX™ O/M 2.0/2.4 Bioabsorbable Fixation System

Indications for Use:
The BioSorbFX O/M 2.0/2.4 System is intended for use in trauma and reconstructive procedures in the midface, maxilla and mandible. Specifically, the device is indicated for use in surgical repair procedures in the treatment of trauma to the midface, maxilla and mandible, and in orthognathic and reconstructive procedures of the midface, maxilla or mandible. The BioSorbFX O/M 2.0/2.4 System stabilizes bone during healing, in conjunction with appropriate postoperative immobilization. Especially in mandible BioSorbFX O/M System must be used in conjunction of appropriate maxillomandibular fixation (MMF).

The BioSorbFX O/M 2.0/2.4 System implants are not intended for use in, and are contraindicated for:

1. Mandibular tumor resection.
2. Situations where internal fixation is otherwise contraindicated e.g., active or potential infection; patient conditions, including blood supply limitations, insufficient quantity or quality of bone; and where patient co-operation cannot be guaranteed (e.g., alcoholism).
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-off
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K011569